Complete Summary

GUIDELINE TITLE

HIV post-exposure prophylaxis for children beyond the perinatal period.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. HIV post-exposure prophylaxis for children beyond the perinatal period. New York (NY): New York State Department of Health; 2004. 20 p. [33 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. HIV post-exposure prophylaxis for children beyond the perinatal period. New York (NY): New York State Department of Health; 2002 Mar. 26 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- July 24, 2008, Ziagen (abacavir sulfate): The U.S. Food and Drug Administration (FDA) has notified the maker of abacavir and abacavir-containing medications of the need to add information to the current BOXED WARNING about the recommendation to test all patients for the HLA-B*5701 allele before starting or restarting therapy with abacavir or abacavir-containing medications.
- September 10, 2007, Viracept (nelfinavir mesylate): Pfizer issued a Dear Healthcare Professional Letter to inform healthcare professionals of the presence of ethyl methanesulfonate (EMS), a process-related impurity in Viracept and to provide guidance on the use of Viracept in pregnant women and pediatric patients.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Hepatitis B virus infection
- Hepatitis C virus infection
- Sexually transmitted diseases
- Sexual assault

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Emergency Medicine
Family Practice
Infectious Diseases
Pediatrics
Preventive Medicine
Psychiatry
Psychology

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Public Health Departments
Social Workers

GUIDELINE OBJECTIVE(S)

To help medical providers identify and treat pediatric patients with potential human immunodeficiency virus (HIV) exposures

TARGET POPULATION

Children beyond the perinatal period with potential human immunodeficiency virus (HIV) exposures

INTERVENTIONS AND PRACTICES CONSIDERED

Initial Evaluation/Risk Assessment

1. Risk assessment to determine whether post-exposure prophylaxis for human immunodeficiency virus (HIV) is indicated
2. Cleansing of wound or irrigation of mouth and eyes, as appropriate
3. Notification of parent or guardian
4. Referral of child to medical facility or emergency room for further evaluation
5. Confidential baseline HIV antibody tests
6. Assessment of risk for other pathogens
7. Blood count (CBC)
8. Liver function tests

Evaluation and Management of Sexual Assault

1. Inclusion of a Sexual Assault Forensic Examiner (SAFE) trained in pediatric examinations on evaluation team
2. Availability of appropriate resources to address medical, psychosocial, and legal issues
3. Assessment of child for risk of sexually transmitted disease, with laboratory evaluation and antimicrobial prophylaxis as appropriate

Treatment/Management/Counseling

1. Discussing benefits and risks of post-exposure prophylaxis with family and child
2. Parental or legal guardian consent
3. Post-exposure prophylaxis for HIV:
    - Children/adolescents 13 years and older:
        - Recommended regimen: zidovudine, lamivudine, and tenofovir
        - Alternative regimen: zidovudine, lamivudine, and nelfinavir
    - Children 13 years or younger:
        - Recommended regimen: zidovudine, lamivudine, and nelfinavir
    - Other medications considered, but not recommended: nevirapine, efavirenz, abacavir
4. Clinical follow-ups to include toxicity assessment, complete blood count, liver function tests, and HIV testing
5. Assessment of psychosocial status and obtaining referrals if needed
6. Post-exposure prophylaxis following exposure to other infectious agents:
    - Hepatitis B vaccine series
    - Hepatitis B immune globulin
    - Determination of serostatus if child has been previously vaccinated

- Determination of hepatitis C serologic status in cases of percutaneous exposure
- Assessment of tetanus vaccination status in cases of percutaneous exposure and administration of tetanus toxoids and tetanus immune globulin if vaccination status is not up-to-date
- Cleansing of bite wounds and administration of antibiotics, as appropriate

Prevention/Counseling

1. Home and school instruction about avoiding potentially risky exposures
2. Age-appropriate discussions between physician and child concerning reduction of risky behaviors

MAJOR OUTCOMES CONSIDERED

- Risk and incidence of human immunodeficiency virus (HIV) transmission after exposure to HIV and after prophylaxis
- Incidence of post-exposure transmission of hepatitis B virus (HBV)
- Adverse effects of HIV post-exposure prophylaxis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person three to four times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Assessment to Determine Whether Post-Exposure Prophylaxis (PEP) is Indicated

- Following an exposure, the clinician should ascertain whether the exposure is associated with a potential risk of human immunodeficiency virus (HIV) transmission and whether it has occurred within the previous 36 hours.
- Types of exposures that should prompt PEP (Table 1 in the original guideline document provides risk calculations for specific exposures):
    - Unprotected vaginal or anal intercourse
    - Oral sex with ejaculation or blood exposure
    - Needle sharing
    - Injuries with exposure to blood from a source known to be HIV-infected
    - Injuries with exposure to blood from a source of unknown HIV status (Including needlesticks, human bites, accidents)
- Once the clinician has determined that a potential risk exposure has taken place, the clinician should:
    - Clean the HIV-exposed wound with warm water and soap. If the mouth or eyes are involved, they should be irrigated copiously with tap water.
    - Notify the parent or legal guardian unless the child/adolescent refuses parental notification and is deemed competent to make such decisions and can legally request that his/her parents not be notified.
    - Refer the child to a medical facility or emergency department for immediate further evaluation of the risk of exposure and the need for PEP.
    - Obtain a confidential baseline HIV antibody test.
    - Assess the risk of exposure to other pathogens, including hepatitis B virus (HBV) and hepatitis C virus (HCV), tetanus, sexually transmitted diseases, and bacterial infections, and treat as necessary (see section below titled, "PEP Following Exposures to Other Infectious Agents").

Special Considerations For Evaluation Of Sexual Assault Exposures

- Evaluation of and treatment for sexual assault should be managed by a multidisciplinary team that is experienced in the care of children or adolescents who have been sexually assaulted.
- A Sexual Assault Forensic Examiner (SAFE) who is trained to perform pediatric examinations should be included on the team whenever possible to assist in the medical examination, coordination of care, and discussions about treatment regimen. A rape crisis counselor and/or child advocacy team should be involved in all cases of sexual assault to assist the child and the family in dealing with the trauma and to assist with referrals.
- Children and adolescents who are sexually assaulted should be managed in an emergency department or other setting where appropriate resources are available to address the medical, psychosocial, and legal issues of such an offense.
- Children who are sexually assaulted should be assessed for the risk of acquiring other sexually transmitted diseases, including gonorrhea, syphilis, chlamydia, hepatitis B, herpes simplex virus, human papillomavirus, bacterial vaginosis, and trichomoniasis. Laboratory evaluation and possible

antimicrobial prophylaxis should be considered depending on the nature of the assault.

Implementing Post-Exposure Prophylaxis

- The clinician should discuss key issues about PEP with the family and child as soon as possible. Key issues include:
    - Potential benefits of HIV PEP
    - Potential toxicities associated with medications
    - Instructions on how and when to give the medications
    - Importance of adherence to the medication regimen
    - Nature and duration of medication regimen and monitoring schedule
- When parental or legal guardian consent cannot be obtained to initiate HIV PEP in a minor, the treatment may be initiated. Parental/legal guardian consent is strongly recommended to continue PEP beyond the first few hours/days. Emancipated minors, married minors, and minors who are parents may provide consent for medical care and treatment.
- Before initiating PEP, the clinician should obtain complete blood count (CBC) and serum liver enzymes.
- The prophylactic medication regimen should be started as soon as possible (ideally within two hours and not more than 36 hours following exposure) and should be continued for 28 days.
- Medications should be made available to the patient in sufficient supply to complete a course of prophylaxis.

Recommended Regimens For Post-Exposure Prophylaxis (please refer to Table 4 in the original guideline document for dosing recommendations)

- For children/adolescents 13 years or older, the suggested PEP regimen is zidovudine, lamivudine, and tenofovir. An alternative PEP regimen for these patients is zidovudine, lamivudine, and nelfinavir (see Table 4 in the original guideline document).
- For children 13 years or younger, the suggested PEP regimen is zidovudine, lamivudine, and nelfinavir (see Table 4 in the original guideline document).
- When the source is known to be HIV-infected and information regarding previous anti-retroviral (ARV) therapy, current level of viral suppression, or genotypic/phenotypic resistance profile is available, the clinician, in consultation with an HIV Specialist, should individualize the regimen to more effectively suppress viral replication.

Follow Up Monitoring for Patients Receiving PEP

- Initial follow-up of the exposed child should occur within 2 to 3 days to review medication regimen, assess psychosocial status of child and family, and arrange appropriate referrals (e.g., psychosocial counseling after sexual assault).
- Clinicians should closely monitor patients receiving PEP to detect ARV-induced toxicities. Arrangements should be made for clinical follow-up at 2 weeks and 4 weeks; CBC and serum liver enzymes should be repeated at 4 weeks (see Table 5 in the original guideline document).
- HIV testing should be repeated at 1, 3 and 6 months after exposure.

- Because of the complexity and potential adverse effects of the PEP regimens, longitudinal care of the exposed patient should be provided either directly by or in consultation with a pediatric HIV Specialist.

Post-Exposure Prophylaxis Following Exposures To Other Infectious Agents

- If the exposed child/adolescent is not fully immunized against hepatitis B, the child/adolescent should complete the hepatitis B vaccine series, with the next scheduled dose being given immediately. If the source is known to be hepatitis B surface antigen positive (HBsAg+), the child should receive hepatitis B immune globulin in addition to completing the hepatitis B vaccine series.
- If the child has been previously vaccinated against hepatitis B, the child's serostatus should be determined. If the child has serologic immunity to hepatitis B, no further action is necessary. If the child does not have serologic immunity but there is documentation of previous vaccination, the clinician should administer a booster vaccine and reevaluate serologic status in 1 month to determine whether full revaccination is necessary.
- The baseline hepatitis C serologic status of the exposed child should be determined in cases of percutaneous exposure. There are currently no recommendations for prophylaxis for hepatitis C virus (HCV). Repeat testing for hepatitis C serologic status should be performed at 6 months. Repeat testing for hepatitis C serologic status or polymerase chain reaction (PCR) for HCV may be considered at 2 to 4 weeks after exposure.
- The tetanus vaccination status of the exposed child should be assessed in cases of percutaneous exposure or bite wound. Tetanus toxoids and tetanus immune globulin should be given if the child's vaccination status is not up-to-date.
- Bite wounds should be cleansed. Antibiotics should be initiated in severe wounds, deep puncture wounds, and wounds to the face, genitals, or extremities.

Preventing Exposures

- Children should be instructed in school and at home about potentially risky exposures and how to avoid them.
- The clinician should discuss reduction of potentially risky behaviors with all children in a manner that is appropriate to their age and developmental stage as a routine component of pediatric care.

CLINICAL ALGORITHM(S)

A clinical algorithm on post-exposure prophylaxis (PEP) beyond the perinatal period is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

These guidelines are based on best-practice evidence and constitute the opinion of the New York State Department of Health (NYSDOH) Committee for the Care of Children and Adolescents with Human Immunodeficiency Virus (HIV) Infection.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Potential Benefits

These guidelines are intended to help medical providers identify and treat pediatric patients with potential human immunodeficiency virus (HIV) exposures. Early identification and treatment may reduce the risk and rate of HIV transmission and viral replication.

POTENTIAL HARMS

Potential toxicities and side effects associated with medication:

- Zidovudine (Retrovir, ZDV): bone marrow suppression, anemia, neutropenia, thrombocytopenia, nausea, myalgia, headaches, hepatotoxicity
- Lamivudine (Epivir, 3TC): pancreatitis, peripheral neuropathy
- Nelfinavir (Viracept): diarrhea, nausea, vomiting, headache
- Tenofovir (Viread)*: renal toxicity, pancreatitis

***Note from the National Guideline Clearinghouse™**: The U.S. Food and Drug Administration's (FDA) MedWatch Safety program distributed information from the manufacturer (Gilead Sciences, Inc) of tenofovir disoproxil fumarate (Viread®) about a high rate of early virologic failure and emergence of nucleoside reverse transcriptase inhibitor (NRTI) resistance associated mutations with the use of the drug in a once-daily triple NRTI regimen along with didanosine enteric coated beadlets (Videx EC, Bristol-Myers Squibb), and lamivudine (Epivir, GlaxoSmithKline). Based on these results, Tenofovir DF in combination with didanosine and lamivudine is not recommended when considering a new treatment regimen for therapy-naïve or experienced patients with HIV infection. Patients currently on this regimen should be considered for treatment modification. For more information, visit the FDA Web site.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are based on best practice evidence and constitute the opinion of the New York State Department of Health (NYSDOH) Committee for the Care of Children and Adolescents With Human Immunodeficiency Virus (HIV) Infection. There are no clinical trials in the pediatric age group to guide decision-making in the management of pediatric post-exposure prophylaxis (PEP) for HIV, and consultation with a pediatric HIV Specialist is recommended.

- No clinical studies are available to determine the best regimens for prophylaxis. The guideline committee's recommendations for drug choices and dosages follow current NYSDOH recommendations for occupational and non-occupational PEP and take into account the current antiretroviral (ARV) therapy recommendations in the NYDOH's *Pediatric Antiretroviral Therapy*. The recommended regimen for children/adolescents 13 years and older provides potent antiviral activity with a low pill burden and minimal side effects; however, tenofovir has not yet been US Food and Drug Administration (FDA)-approved for children under age 18.
- Although in general the NYSDOH recommends a three-drug regimen for PEP, the Committee did not reach consensus. Some believed that the issues of toxicity and poorer adherence with a three-drug regimen warranted use of a two-drug regimen in some cases. Others believed that a three-drug regimen was always preferable. More recently available formulations of medications include combination pills and once daily dosing that are more convenient. These have not been extensively studied in the context of PEP but have been proven effective in the treatment of HIV infection.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (*HIV clinical practice guidelines*, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience
- Define target audience (providers, consumers, support service providers).
    - Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)?
- Define implementation methods.
    - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes.
    - What steps need to be taken to make these activities happen?
    - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?

    - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
    - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor progress.
    - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate.
    - Did the processes and strategies work?
    - Were the guidelines implemented?
    - What could be improved in future endeavors?

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. HIV post-exposure prophylaxis for children beyond the perinatal period. New York (NY): New York State Department of Health; 2004. 20 p. [33 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Mar (revised 2004)

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Committee for the Care of Children and Adolescents with HIV Infection

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. HIV post-exposure prophylaxis for children beyond the perinatal period. New York (NY): New York State Department of Health; 2002 Mar. 26 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- HIV post-exposure prophylaxis for children beyond the perinatal period. Tables and recommendations. New York (NY): New York State Department of Health; 2004 Oct. 15 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.
- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

This guideline is available as a Personal Digital Assistant (PDA) download from the New York State Department of Health AIDS Institute Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was prepared by ECRI on January 21, 2004. This NGC summary was updated by ECRI on February 3, 2005. This summary was updated by ECRI Institute on October 2, 2007, following the U.S. Food and Drug Administration advisory on Viracept (nelfinavir mesylate). This summary was updated by ECRI Institute on August 11, 2008 following the U.S. Food and Drug Administration advisory on Ziagen (abacavir sulfate).

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